Office Supreme Court, U.S.
FILED
JUL 28 1984
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84-170

NO.

IN THE

Supreme Court of the United States

October Term, 1983

IMPRO PRODUCTS, INC.,

Petitioner,

v.

JOHN R. BLOCK
Secretary of Agriculture of
the United States,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR
THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTIONS PRESENTED

1. Whether the decisions of this Court in *Holmberg* v. *Armbrecht* and *Russell* v. *Todd* have been superseded by the recodification of the general federal statute of limitations, 28 U.S.C. § 2401(a).

2. Whether the general federal statute of limitations, 28 U.S.C. § 2401(a), is applicable to an action in which the sole and exclusive remedy available is equitable in nature.[1]

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[1]The caption of the case in this Court contains the names of all parties in the Court of Appeals. The Petitioner, Impro Products, Inc., is a closely held company and other than certain family-owned trusts has no parent subsidiary or affiliated companies.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Petitioner, Impro Products, Inc., respectfully prays that a Writ of Certiorari be issued to review the judgment of the United States Court of Appeals for the District of Columbia Circuit filed on December 16, 1983.

OPINIONS BELOW

The opinion of the Court of Appeals, dated December 16, 1983, is officially reported at 722 F.2d 845, and is reprinted in the Appendix hereto beginning on page A-1. The order of of the Court of Appeals denying rehearing to Petitioner is reprinted in the Appendix on page A-16. The opinion of the United States District Court for the District of Columbia was not officially reported, and is reprinted in the Appendix hereto beginning on page A-17.

JURISDICTION

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). The judgment of the Court of Appeals was entered on December 16, 1983. Petitioner's Motion for Rehearing was denied by the Court of Appeals on March 1, 1984. On May 23, 1984, The Chief Justice extended the time for filing this Petition to July 29, 1984.

PROVISIONS OF STATUTES INVOLVED

7 USC § 430

> The Secretary of Agriculture may purchase in the open market from applicable appropriations samples of all tuberculin, serums, antitoxins, or analogous products, of foreign or domestic manufacture, which are sold in the United States, for the detection, prevention, treatment or cure of diseases of domestic animals, test the same, and disseminate the results of said tests in such manner as he may deem best.

28 USC § 2401(a)

> Except as provided by the Contract Disputes Act of 1978, every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues.

STATEMENT OF THE CASE

This is an equitable action instituted in the United States District Court for the District of Columbia on June 4, 1981, in which the Petitioner sought and obtained an injunction barring the United States Department of Agriculture (USDA) from further releasing copies of a report issued by

it regarding a test conducted by USDA of one of Petitioner's products, which was found by the District Court to contain false and misleading statements.[1] The District Court also ordered that any report on the test released by USDA must contain a fair and accurate account of the problems involved in the conduct of the test. The decision was subsequently reversed by the Court of Appeals for the District of Columbia Circuit, on the grounds that the initial release of the report occurred prior to the six year period of the general federal statute of limitations, 28 U.S.C. § 2401(a).

The report which is the subject of this action was published in the American Journal of Veterinary Research.[2] The District Court found that the report on the test contained "several false or misleading statements" and that the release of the report by USDA constituted "arbitrary and capricious action and an abuse of discretion." The court stated that "the most glaring inaccuracy" in the report was that "each treated cow was inoculated [with Petitioner's product] . . . 5 to 7 days before the anticipated date of calving,"[3] whereas in fact "fewer than one third of the

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[1]The test was for the purpose of determining the efficacy of Petitioner's product in increasing milk production. The test animals included two herds of daily cows at the USDA research station at Beltsville, Maryland and eight private dairy herds in Maryland. There were over 400 cows involved in the test, of which approximately one-half were supposed to have been treated with Petitioner's product, and the remainder injected with a placebo.

[2]The report is reprinted in the Appendix hereto beginning on Page A-27.

[3]Injections during that time period would have been compatible with the directions for the use on the label of Petitioner's product and with the protocol established by USDA for the test. (Planitiff's exhibit 17, 250-3, transcript 30-31, 55-56, Rec. 137H, at 103).

treated cows were actually injected" during the period.[4] The District Court also found that the report did not reveal that data from two distinct herds were combined even though there was "general agreement amongst the scientists involved here that between-herd comparisons are not valid in tests such as this." Moreover, the data from one of those herds showed that Petitioner's product "provided a significant increase in milk production," but the combining of that data with that of another herd "masked evidence of the effectiveness" of Petitioner's product. The Court further found that the report did not reveal that crossbred cows were used in the test and the use of crossbreeds is significant because "they are generally considered unpredictable" and there are no mature equivalent factors" for crossbreeds which "are essential for analyzing data in a milk production study."

In its appeal of the decision of the District Court, USDA did not present any issue regarding the validity of the findings of the District Court regarding the false and misleading statements in the report. The only issues presented to the Court of Appeals were: (a) whether USDA's action was reviewable, (b) whether the District Court conducted a trial *de novo*, (c) whether the suit was timely filed, and (d) whether counterclaims by USDA should have been dismissed. The Court of Appeals held the

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[4]In answer to an interrogatory USDA admitted that the statement in the report regarding the injection of the treated cows during the 5 to 7 day period was false (Rec. 94, Interrogatory No. 7), and an official of USDA testified that "less than 20 percent or so, or less, were given the product in that time period interval . . . there weren't enough animals remaining to make any valid conclusions". (Rec. 137E at 560) Furthermore, one of the USDA scientists involved in the test testified that the statement regarding the injection of the cows was not true. (Rec. 144A at 234-235).

statute of limitations set fourth at 28 U.S.C. § 2401(a) to be applicable to suits in equity as well as to actions at law, and reversed the order of the District Court on the basis that the suit was not filed within the six year period required by that statute.[5] The Court of Appeals affirmed the dismissal by the District Court of certain counterclaims that had been filed

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[5]The Court held that the six year limitation applied since the initial decision to publish and disseminate the report was made more than six years prior to the institution of the suit and "Impro points to no evidence suggesting that a conscious, independent decision was made with any subsequent reissuance." However, the Court was in error since Impro did point to such evidence, including reference to many examples of occasions during that period in which USDA received inquires from the public for information concerning Impro, in response to which USDA not only had to make decisions as to the availability of the information under the Freedom of Information Act (5 U.S.C. § 552(a) (3)) but also made "conscious, independent decisions" as to what information to send to members of the public, including decisions as to whether to send reprints of the USDA report on the Beltsville test to Petitioner's product. (Plaintiff's Exhibits 151, 157, 157A, 157B, 157c, 162, 164, 165, 242, 243). Furthermore, in 1978, pursuant to the request of a Congressional Subcommittee, USDA reviewed the matter. During the Subcommittee hearing, the attention of USDA was called to the false statements in the report regarding the injection of the cows. (Antibodies in Animal Health Maintenance, Hearings Before the Subcommittee on Dairy and Poultry of the Committee on Argiculture, House Representatives, 95th Cong., 2nd Sess. 1978), Plantiff's Exhibit 188-A, at 32-33, 58-59). Nevertheless, USDA concluded that no change should be made and continued to distribute the report pursuant to inquires about Impro (See e.g., Plantiff's Exhibit 242 (March 13, 1981) and 243 (June 26, 1981). In addition, pursuant to the request of a USDA Administrator, counsel for Petitioner sent the Adminstrator a letter dated March 2, 1981, detailing many of the false statements in the report, including the one regarding the injection of the cows (Plaintiff's Exhibit 241-A). After the matter was reviewed, the Administrator sent a letter to Petitioner's counsel stating that the "Department officials had acted with propriety" and USDA continued to distribute the false report thereafter. (Plaintiff's Exhibit 243 (June 26, 1981).

by USDA, and remanded the case to the District Court for further proceedings regarding a constitutional claim which the District Court had not addressed. The court admonished the District Court, however, that "...if Plaintiff indeed asserts a colorable constitutional claim, the District Court must determine whether it satisfies the six-year statute of limitations for civil actions against the United States. 28 U.S.C. §2401(a) (Supp. V 1981)". 722 F. 2d at 851, n. 12.

REASONS FOR GRANTING THE WRIT

I. THE DECISION OF THE COURT OF APPEALS CONFLICTS WITH APPLICABLE DECISIONS OF THIS COURT.

The decision of the Court of Appeals conflicts with the decisions of this Court in *Holmberg* v *Armbrecht*, 327 U.S. 392 (1946) and *Russell* v *Todd*, 309 U.S. 280 (1940).

After the merger of law and equity in the Federal Rules of Civil Procedure, which became effective in 1938,[6] questions arose whether statutes of limitations applied to cases in which equitable relief was sought but which could have been redressed by either a legal or equitable remedy or where the equitable relief was sought in aid of the legal right. In the *Russell* case this Court held that:

> [W]hen the [equitable] jurisdiction of the federal court is concurrent with that at law, or the suit is brought in aid of a legal right, equity will withhold its remedy if the legal right is barred by the local statue of limitations[7]

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[6]28 U.S.C., Appendix at Page 394, Notes relating to Rules 1 and 2; 3 *Moore's Federal Practice*, § 201, 206 (a))

[7]Citations omitted.

> But where the equity jurisdiction is exclusive and is not exercised in aid or support of a legal right, state statutes of limitations barring actions at law are inapplicable, and in the absence of any state statute barring the equitable remedy in like cases, the federal court is remitted to and applies the doctrine of laches as controlling.

309 U.S. at 289.

> The Court in *Russell* thus concluded:
> Here the jurisdiction being exclusively in equity to enforce rights cognizable only in equity, statutes barring legal causes of action . . . are not controlling . . . .

309 U.S. at 291.

Like the *Russell* case, *Holmberg* involved a federally created equitable right, i.e., an action to enforce a statutory liability of stockholders of a farm loan bank under the Federal Farm Loan Act (formerly 12 U.S.C. § 812). This Court held in *Holmberg* that:

> The present case concerns not only a federally-created right but a federal right for which the sole remedy is in equity . . . When Congress leaves to the federal courts the formulation of remedial details, *it can hardly expect them to break with historic principles of equity in the enforcement of federally-created equitable rights.*
>
> *Traditionally and for good reasons, statues of limitation are not controlling measures of equitable relief.*

327 U.S. at 395-396, (emphasis added).

In the instant case the only available remedy is in equity and therefore under the doctrine established in *Russell* and *Holmberg*, no statue of limitations is applicable.

II. THE DECISION BELOW ALSO CONFLICTS WITH TWO CIRCUIT COURT OPINIONS.

The decision of the Court of Appeals in the instant case is also in conflict with the majority opinion of that Court in *Saffron* v *Department of the Navy*, 561 F.2d 938 (D.C. Cir. 1977), cert. denied 434 U.S. 1033 (1978). In that case a Navy employee who had been dismissed as a civilian mechanic sought judgment setting aside his removal from federal service, reinstating him in the job, and awarding him damages. The court discussed the concurrency doctrine, under which a case involving a remedy in equity as well as at law is governed by a statute of limitation, whereas one involving solely equitable relief is governed by the doctrine of laches. The court pointed out that: "Even prior to unification of district court proceedings in one form of action [in 1938], it had become well settled that whenever the courts of law and equity possessed concurrent jurisdiction to enforce the claimant's right, statutes of limitation were to be as forcefully applied in equity as at law," and that the distinction between suits involving actions at law and actions involving both law and equity, and suits in which the relief sought was purely equitable in character, "had survived four decades of merger of common law and equity procedure in the federal courts" 561 F 2d at 941, 942. The court held that the facts in that case involved both restoration of employment, an equitable relief, and damages, an action at law, and that:

> This, we find, is the kind of parallelism that demonstrates applicability of the concurrency rule. *As we read the Supreme Court's pronouncements on the subject, only when a court is importuned "to enforce rights cognizable only in equity [are] statute[s] barring legal causes of action . . . not controlling.*[37] [Footnote citing the

> *Russell* and *Holmberg* cases] . . .Additionally to the binding effect of the Supreme Court's exposition of federal law, this view is thoroughly consistent with our own rather numerous holdings in the area as well as that of other Courts.

561 F.2d at 943 (footnote omitted)

The court in the *Saffron* case described the statute of limitation set forth at 28 U.S.C. § 2401(a) as "part of the Tucker Act—century old legislation by which district courts share with the Court of Claims jurisdiction over suits against the United States." 561 F. 2d at 944. The Court pointed out that in 1964 and 1972 the powers of the two courts were aligned with respect to monetary claims and injunctions. The court held that under the facts of the *Saffron* case, if the statute of limitation in 28 U.S.C. § 2401(a) was not applied "it would allow the claimant to pursue in a district court an objective he could not aspire to in the Court of Claims, and thereby upset the congruity for which Congress ever so recently has striven" and thus the court rejected the argument that "Section 2401(a) does not extend to the equitable as well as the common law features" of the case. 561 F 2d at 946.

One of the panel judges in the *Saffron* case issued a concurring opinion on the basis that 28 U.S.C. § 2401(a) applies to all actions and that the purpose of the provision was "to lay to rest the ancient distinctions" between actions involving both equitable and law claims and those involving solely and exclusively equitable claims. 561 F. 2d at 946. That judge based his view upon the 1948 recodification of the Judicial Code in which the word "suits" in 28 U.S.C. § 2401 (a) was changed to " civil action". However, it is clear from the legislative history of the 1948 recodification that Congress did not intent to "lay to rest the ancient distinc-

tions" between actions involving equitable relief as well as relief at law and suits involving solely and exclusively equitable relief. The revisers of the 1948 recodification were keenly aware of the general rule, stated in *United States* v *Ryder,* 110 U.S. 729 (1884), that "[i]t will not be inferred that the legislature, in revising and consolidating the laws, intended to change their policy, unless such intention be clearly expressed" See Barron, *The Judicial Code: 1948 Revision,* 8 F.R.D. 439, 445-446 (1948). As this Court held in *Tidewater Oil Co.* v *United States,* 409 U.S. 151, 162-163 (1972), a change in substance is not to be inferred where the Reviser's Notes do not indicate an intent to change the law. The Reviser's Notes regarding the 1948 recodification state that 28 U.S.C. § 2401 "consolidates provisions in section 41 (20) of Title 28 U.S.C. 1940 ed., as to the time limitation for bringing actions against the United States under section 1346(a) of this Title, with Section 942 of said Title 28." [the Federal Tort Claims Act]. (H.R. Rep. No. 308, 80th Cong., 1st Sess. A185 (1947)). The change of the word "suit" to "civil action" in § 2401(a) was described by the Reviser's Notes as merely a "[c]hange... in phraseology." (H.R. Rep. No. 308 *supra,* at A185). In *Richardson* v *Morris,* 409 U.S. 464 (1973), this Court refused to find any substantive significance in a similar change of language in 28 U.S.C. § 1346(a), i.e. "[a]ll claims" was changed to" "[a]ny other civil action or claim" which it was contended broadened the scope of the district court's jurisdiction to include "actions" for injunctions as well as "claims" for monetary damages. This Court held, however, that there was no "suggestion that the change was to affect the section's substance." 409 U.S. at 465 n. In defending against suits brought under the Federal Tort Claims Act, the United States has successfully argued that § 2401 (a) and (b) only restate prior law. *See e.g., United States v Glenn,* 321 F. 2nd 884, 886 (9th Cir.), cert. denied, 352 U.S. 926 (1956)).

The opinion of the concurring judge in *Saffron* and the court's opinion in the instant case not only are in conflict with the opinion of the majority panel in *Saffron*, which relies upon the *Russell* and *Holmberg* cases, they are also in conflict with the opinion of the Court of Appeals for the Seventh Circuit in *Nemkov* v. *O'Hare Chicago Corp.*, 592 F. 2nd 351 (7th Cir. 1979) in which the court stated:

> Distinctions between legal and equitable remedies are not often necessary in the federal courts, where law and equity are merged under the Federal Rules of Civil Procedure. For the purpose of determining whether laches or a statute of limitations is applicable to a claim based on a federal right, however, that distinction is controlling. *In the federal courts the statute of limitations yields to the doctrine of laches only in cases in which equitable jurisdiction is "exclusive" and not "concurrent"* . . . .
>
> ***
>
> In the *Russell* and *Holmberg* cases, the sole remedy was in equity, and therefore laches rather than the statute of limitations applied.

592 F.2d at 354. (emphasis added)

The Court of Appeals in the instant case failed to recognize the distinction between cases where the concurrency doctrine is applicable and suits in which solely and exclusively equitable relief is available. In ruling that the statute of limitations applies where the sole remedy is in equity, and thus to the instant case, the court mistakenly relied upon the concurring opinion in the *Saffron* case and on *Werner* v. *United States*, 188 F.2nd 266, 268 (9th Cir. 1951); *Screven* v. *United States*, 207 F. 2d 740, 741 (5th Cir. 1953); *Heritage Pulman Bank & Trust Co.* v. *United States*, 480 F. Supp. 54, 57 (N.D. Ill. 1979) and *Crown Coat*

Front Co. v. *United States*, 386 U.S. 503 (1967).[8] Each of those cases, however, involved *both* equitable and monetary claims directly or indirectly, and thus came under the concurrency doctrine, rather than involving solely and exclusively equitable relief, as in the instant case.

III. THIS CASE PRESENTS PUBLIC POLICY ISSUES OF MAJOR IMPORTANCE

The issues in this case revolve around two important public policy interests—integrity in scientific reporting and integrity in Government. The District Court found that USDA issued a false and misleading report on the test conducted by USDA on one of the Petitioner's products and the Court discussed in some detail four basic false and misleading areas in the report. As pointed out *supra*, USDA admitted that the statement in the report that "each treated cow was inoculated subcutaneously.. [with Petitioner's product] 5 to 7 days before the anticipated date of calving" was false. Also as pointed out *supra*, one of the USDA scientists involved in the test testified that the statement regarding the injection of the cows was not true and another official of USDA testified that not only were there less than 20% of the cows so injected, there were not enough remaining cows (those properly injected) as a basis for any valid conclusions concerning the test. Furthermore, a bio-statistician who was called by USDA as an expert witness testified on cross-examination that if only 25% of the cows were properly injected, there would

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[8] *Werner* involved reformation of a lease and money damages; *Screven* involved a claim for the value of realty alleged taken by the United States in condomnation proceedings; *Heritage* involved the recovery of proceeds under National Service Life Insurance; and *Crown Coat Front Co.* involved a contract dispute and was not a suit for purely non-monetary relief.

be only a 10% chance that a significant increase in milk production would be detected (Wyant, Transcript at 623-625).

The evidence in this case establishes that USDA knew before the report was published that the statement regarding the injection of the cows was false. A USDA employee, whose role in the test was to collect data from the various herds involved and compile data regarding the test, testified that during the course of the test he observed that a number of the cows had not been properly injected or had been injected with the wrong solution, i.e. with the placebo rather than Petitoner's product or vice-versa, and he promptly advised the chief scientist involved in the test of those errors. He also discovered that the injection dates were not listed for many cows, and others were listed as "probably injected" and "group numbers not listed" meaning that it was not known whether those cows had been injected with Petitioner's product or with the placebo. Also prior to the publication of the USDA report that same employee prepared a tabulation regarding the injection of each cow involved in the test. The tabulation readily revealed that most of the cows were not properly injected. At that time USDA also had lists showing the anticipated date of calving for each cow.

It is clear, therefore, that USDA knew before the report was published that the statement in the report regarding the injection of the cows was false. Also subsequent to the publication of the report the untruthfulness of that statement had been called to the attention of USDA. For example, in 1978, USDA, pursuant to a request of a Congressional Subcommittee, engaged a professor at the University of Arizona to review the matter. (Plaintiff's Exhibit 188-A, at 58-59). In his report to USDA the professor stated that: "[A] major criticism levelled at the Belts-

ville trial . . . is that the innoculation schedule in the experimental protocol was a not followed. The statement is true, since not all the inoculations were given in the 5-10 day prepartum period spelled out". (Defendant's Exhibit 128, at 4). Even though on this additional occasion USDA was informed that the statement in the report on the test regarding the injection of the cows was false, USDA refrained from so advising the Congressional Subcommittee and continued to rely upon and widely distribute the false and misleading report.

Prior to filing the suit Petitioner's counsel, at the request of a USDA Administrator, sent a letter to the Administrator detailing many of the false statements in the report on the test, including the false statement regarding the injection of the cows. Two month later Petitioner's counsel received a response from the Administrator stating that he had satisfied himself that "Department officials have acted with propriety". (Plaintiff's Exhibits 241-A, 242-A.) Throughout this litigation USDA has contended that under the provisions of 7 U.S.C. § 430, the Secretary of Agriculture has unreviewable discretion to issue any kind of a report on a scientific test, including the one involved in this case containing false and misleading statements of a material nature.

Thus, USDA knew before the report on the test was published that most of the treated cows had not been injected with Petitioner's product within the prescribed time period, the false and misleading statement in the report was specifically called to the attention of USDA officials in 1978 and again in 1981 prior to the filing of this suit, and USDA admitted in answer to a pretrial interrogatory that the statement was not true. USDA nevertheless continued to rely upon and widely disseminate and defend the false report. The reversal by the Court of Appeals, on

the basis of the statute of limitations, results in a situation in which, since USDA was able to rely upon and disseminate the report for a sufficient period of time, USDA is now free to resume reliance upon and dissemination of the report even though the District Court found that the report was false and misleading and USDA has admitted that a fundamental statement in the report regarding the injection of the cows is not true. This result is not compatible with the purposes of the statute of limitations.[9] Moreover, this case presents serious public interest questions regarding integrity in scientific reporting as well as integrity in Government.

There have been many instances in recent years of scientific fraud and false scientific reporting.[10] The Department of Justice has sought criminal sanctions on several occasions against researchers responsible for submission of false reports to Federal regulatory agencies.[11] In fact, had the report involved in this case been prepared by Petitioner and submitted to USDA, Petitioner also would have been subject to criminal prosecution. This results in a

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[9]See, e.g., *Burnett* v. *New York Central R. Co.*, 380 U.S. 424 (1965).

[10]See e.g., *Fraud in Biomedical Research,* Hearings Before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, 95th Cong., First Sess. (1981); Broad and Wade: *Betrayers of Truth; Fraud and Deceit in the Hall of Science, Simon & Schuster,* 1982.

[11]For example, on April 28, 1983, *The Washington Post* reported at page A8 that a surgeon faced up to 10 years in prison and a $10,000.00 fine after pleading guilty to preparation of false data for submission to the Food and Drug Administration. Also, on April 30, 1983, *The Washington Post* at page B5 reported that a physician was fined $1,000.00 after pleading guilty to creating false results in research on a drug requiring FDA approval. The *New York Times* reported on January 23, 1981, that four corporate officials had been indicted for, among other things, Concealing relevant information in a report of FDA regarding the testing of drugs.

double standard of integrity--a high standard of integrity in scientific reporting by private parties, but no standard at all for the Government. It is difficult to reconcile the fact that one arm of the Department of Justice is criminally prosecuting private parties for false reports on scientific tests with the fact that another arm of the Department is defending USDA with respect to the report on the test of Petitioner's product which USDA *admits* contains a fundamental false statement regarding the injection of the test animals.

In the *Russell* and *Holmberg* cases this Court settled the question whether statutes of limitation are applicable to actions involving solely and exclusively equitable relief. However, in recent years considerable confusion has arisen concerning the doctrine set forth in those cases in light of the concurrency doctrine.

This case squarely presents the question whether the doctrine set forth by this Court in the *Russell* and *Holmberg cases* is still controlling or whether that doctrine has been overruled by the recodification of 28 US.C. § 2401(a), thereby directing the courts "to break with historic principles of equity in the enforcement of federally-created equitable rights" (*Holmberg*, 392 U.S. at 395), even though the legislative history of § 2401(a) contains no express intent to do so and in fact indicates an intent that there be no change in substance in the statute of limitations.

Accordingly, just as in the *Holmberg* case, the instant case "raises a question of considerable importance in enforcing liability under federal equitable enactments." 327 U.S. at 394. It is respectfully submitted, therefore, that issuance of a Writ of Certiorari in this case would resolve the state of confusion and conflict now existing with

respect to whether 28 U.S.C. 2401(a) was substantially changed by the recodification in 1948 and whether that section now applies not only where the concurrency doctrine is applicable but also where the sole and exclusive remedy available is in equity. Certiorari would otherwise serve the interests of justice as well, especially in this case which raises grave public interest questions as to a lack of integrity in scientific reporting and a lack of integrity in Government.

CONCLUSION

For the reasons stated, a Writ of Certiorari should issue to review the judgment of the Court of Appeals for the District of Columbia Circuit.

Respectufully submitted,

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APPENDIX

APPENDIX A

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 82-2447

IMPRO PRODUCTS, INC.

v.

JOHN R. BLOCK, SECRETARY OF AGRICULTURE OF THE UNITED STATES

Appeal from the United States District Court
for the District of Columbia

(Civil Action No. 81-1284)

Argued September 8, 1983

Decided December 16, 1983

Michael J. Ryan, Assistant United States Attorney, with whom *Stanley S. Harris*, United States Attorney, *Royce C. Lamberth*, *R. Craig Lawrence*, *John H.E. Bayly, Jr.*, Assistant United States Attorneys, and *Raymond W. Fullerton*, Assistant General Counsel, and *Aaron B. Kahn*,

Attorney, Department of Agriculture were on the brief, for appellant.

Harold M. Carter with whom *Philip C. Jones* was on the brief, for appellee. *George T. Qualley* also entered an appearance for appellee.

Before WRIGHT, WALD and EDWARDS, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* EDWARDS.

EDWARDS, *Circuit Judge*: This appeal is the by-product of a protracted dispute between Impro Products, Inc. ("Impro") and the Department of Agriculture ("USDA"). In 1981, Impro filed suit claiming that USDA had improperly distributed reprints of an article that contained allegedly false and misleading information about an Impro product. The disputed article, published in 1970 in the American Journal of Veterinary Research, discussed a USDA study of the efficacy of a veterinary product manufactured by Impro. After hearing, the District Court enjoined USDA from releasing copies of the article and also ordered the Department to attach explanatory information to any other disseminated report on the USDA test of Impro's product.

As a preliminary matter, there is reason to question whether there was any "final agency action" subject to judicial review under the Administrative Procedure Act ("APA"). However, even assuming that there was such agency action, we hold that review in the District Court was barred by the statute of limitations. Accordingly, we reverse the decision and order of the District Court and remand this case for further proceedings consistent with this opinion.

I. BACKGROUND

Almost twenty years ago, in 1965, Impro applied to USDA under the Virus, Serum and Toxin Act of 1913, 21 U.S.C. §§ 151-158 (1976) ("VST Act"), for a license

to produce, ship and sell a veterinary product later named "Whey Antibody Blend." The VST Act makes it unlawful to ship interstate any unlicensed virus, serum, toxin or "analogous product" intended for treatment of domestic animals. *Id.* § 158. Impro claimed the product improved the health and milk production of cows if properly administered.

Initially, the Veterinary Biologics Division of USDA issued a temporary license to Impro to market Whey Blend. The temporary license expired in September 1967 and, since that date, USDA has denied further Impro applications for a license to market Whey Blend. Impro has never sought judicial review of the denials of its license applications.

In 1966, scientists in the USDA Agriculture Research Service ("ARS") reviewed the Impro license application, decided its supporting data were inadequate, and undertook their own study of the efficacy of Whey Blend. ARS scientists met with Impro representatives and worked out a protocol by which to test the product. Testing began in October 1966 at the Beltsville, Maryland, ARS facility, and was completed in December 1967. ARS scientists concluded that the Beltsville test results did not support Impro's claim of efficacy.[1] Thereafter, ARS scientists wrote an article summarizing the ineffectiveness of Whey Blend, as reflected in the test results, which was submitted to and published in the August 1970 issue of the American Journal of Veterinary Research ("AJVR"). Smith, Kiddy, Plowman, Schultze & Hooven, *Whey Antibody Preparation: Effects of Prepartum Injection on Milk Production in Dairy Cows*, 31 AM. J. VETERINARY RESEARCH 1485 (1970), *reprinted in* J.A. 83-86. Since publi-

[1] The District Court, however, found that procedures and objectives of the Beltsville test deviated from the project outline. *Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 4-5 (D.D.C. Sept. 2, 1982) (Memorandum and Order), *reprinted in* Joint Appendix ("J.A.") 71-72.

cation, and as recently as October 15, 1981, USDA regularly has released copies of the article, often coupled with a statement that Impro has no license to sell Whey Blend in the interstate market.[2] From 1969 to the present, Impro has doggedly attacked the Beltsville test results, and has submitted materials to USDA criticizing the test and its results. USDA repeatedly responded that it believed the test was sound, most recently on May 8, 1981. *See Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 4-5 (D.D.C. July 9, 1982) (Memorandum and Order), *reprinted in* J.A. 52-53.

After receiving the May 8, 1981, correspondence, Impro filed this action. It alleged that the Beltsville test was not properly conducted and that the AJVR article contained false and misleading information about Impro's product. Impro requested District Court review of USDA actions taken pursuant to the VST Act—which authorizes USDA to license products—and of actions taken in violation of its Fifth Amendment right to due process. Specifically, Impro sought a declaratory judgment that the test was unreliable and fallacious, and an injunction proscribing USDA's distribution of, and reliance on, the Beltsville test and the AJVR article. The Government counterclaimed, arguing first, that Impro had sold its product interstate without a license, and that such sales should be declared a public nuisance and enjoined; and second, that such sales violated the VST Act and should

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[2] Under 7 U.S.C. § 430 (1982), the Secretary is authorized to test products and disseminate the results of the tests. The section provides:

> The Secretary of Agriculture may purchase in the open market from applicable appropriations samples of all tuberculin, serums, antitoxins, or analogous products, of foreign or domestic manufacture, which are sold in the United States, for the detection, prevention, treatment, or cure of diseases of domestic animals, test the same, and disseminate the results of said tests in such manner as he may deem best.

accordingly be enjoined. The Government also entered an array of defenses, among them that neither the Beltsville test nor the subsequent publication of its results were "agency action" subject to review, and that any suit for judicial review was barred by the statute of limitations. *See Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 5-6 (D.D.C. July 9, 1982) (Memorandum and Order), *reprinted in* J.A. 53-54.

In a series of rulings, the District Court addressed each of these issues. In deciding the issues pertinent to our review, the court first held that the VST Act makes certain action illegal but provides for no civil injunctive relief. It therefore declined to imply such a remedy on behalf of the Government. *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. Apr. 7, 1982) (Memorandum and Order), *reprinted in* J.A. 38-46. Second, the court ruled that Impro's complaint stated an actionable claim that was not time-barred. The court concluded that dissemination of the Beltsville test results was "agency action" subject to judicial review under 5 U.S.C. § 702,[3] and that final agency action occurred in 1981, *i.e.*, on the last of many occasions when USDA officials refused to abandon or modify the Beltsville test results. *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. July 9, 1982) (Memorandum and Order), *reprinted in* J.A. 49-59. Third, the court found that the appropriate standard of review of the challenged agency action was whether the actions were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. July 28, 1982) (Memorandum and Order), *reprinted in* J.A. 60-67. Fourth,

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[3] In fact, the District Court judge ruled first that both the conduct of the test and dissemination of the results were agency action. Subsequently he reconsidered that ruling and determined that the conduct of the test was not subject to review. *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. July 28, 1982) (Memorandum and Order), *reprinted in* J.A. 60-67.

the District Court concluded that the AJVR article contained false and misleading statements, that its release in its current form constituted arbitrary and capricious action and an abuse of discretion, and that dissemination in its current form should be enjoined. *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. Sept. 2, 1982) (Memorandum and Order), *reprinted in* J.A. 68-82.

On appeal, the Government challenges each of the rulings against it.

II. Discussion

A. *The Existence of "Agency Action"*

We begin our inquiry with a consideration of whether the agency's behavior in this matter was properly subject to judicial review. The Administrative Procedure Act subjects to judicial review "final agency action" for which there is no other adequate remedy in a court. APA § 10(c), 5 U.S.C. § 704 (1982). For there to be "final" agency action, there must, of course, be "agency action." A threshold question therefore is whether "agency action" has occurred. The APA defines "agency action" to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." APA § 2(g), 5 U.S.C. § 551(13) (1982). The District Court held that the agency's decision to release the test results, made pursuant to 7 U.S.C. § 430, *see* note 2, *supra*, satisfied the statutory "agency action" language. Case law from this Circuit, however, suggests otherwise.

Thirty-five years ago, this court held, in *Hearst Radio, Inc. v. FCC*, 167 F.2d 225 (D.C. Cir. 1948), that an agency decision to disseminate information it had gathered on its own did not amount to "agency action." In *Hearst Radio*, the FCC published a report entitled "Public Service Responsibility of Broadcast Licensees," known as the "Blue Book." One section of the report contained allegedly false and distorted misrepresentations directed at

WBAL, one of plaintiff Hearst's broadcast stations. Plaintiff sought a declaratory judgment that it was entitled, as a matter of law, to withdrawal of the unwarranted charges and misrepresentations in the Blue Book. It argued that it had suffered a legal wrong as a result of the agency's action—the decision to publish—and therefore had a right to judicial review under the Administrative Procedure Act. The District Court dismissed the action and this court affirmed, holding that plaintiff had presented a claim of libel, but that no statutory agency action was implicated.

The court in *Hearst Radio* first noted that the APA "does not provide judicial review for everything done by an administrative agency," 167 F.2d at 227, and then recited the limits posed by the statutory definition of "agency action," a definition that remains substantially the same today.[4] The court concluded:

> Broad as is the judicial review provided by the Administrative Procedure Act, it covers only those activities included within the statutory definition of "agency action." That definition obviously does not cover an act such as the publication of the Blue Book. It follows that the judgment of the District Court must be affirmed.

Hearst Radio, 167 F.2d at 227. *See also Kukatush Mining Corp. v. SEC*, 309 F.2d 647, 652 (D.C. Cir. 1962) (Bazelon, J., dissenting) (SEC's publication of "Canadian Restricted List," naming Canadian corporations whose securities SEC had reason to believe were being distributed in violation of U.S. securities laws, not "agency action" reviewable under APA) (citing *Hearst Radio*); *Pharmaceutical Manufacturers Association v. Kennedy*, 471 F. Supp. 1224 (D. Md. 1979) (proposed release by FDA of list of therapeutically equivalent

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[4] The only difference is that the statutory words "whole or a part of *an* agency rule," *see* p. 6, *supra*, have replaced the words "whole or part of *every* agency rule." (emphasis added).

drugs, comparing pharmaceuticals containing identical generic active ingredients, and of guide to prescription drug prices, both of which were alleged to be false and misleading, held not agency action). Having found no agency action, the court in *Hearst Radio* ceased its inquiry and never even considered the existence of "*final* agency action."

Hearst Radio is not readily distinguishable from the case before us, and it leaves us with serious doubts as to whether USDA's dissemination of the article amounts to reviewable agency action.[5] Both cases involve an agency decision to disseminate information it has gathered that is potentially harmful to the plaintiff. In both *Hearst Radio* and the case before us, moreover, the agency publication is alleged not only to be defamatory but also to be a knowing misrepresentation.

Despite its obvious relevance, we nonetheless have reason to question the continued validity of the *Hearst Radio* decision, particularly in a case such as this one in which there is a specific statutory authorization for dissemination of information.[6] The *Hearst Radio* doctrine has not

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[5] The District Court relied on *Sears, Roebuck & Co. v. GSA*, 384 F. Supp. 996, 1001 (D.D.C.), *aff'd*, 509 F.2d 527 (D.C. Cir. 1974), for the proposition that agency release of information amounts to agency action. In so doing, the District Court overlooked a crucial distinction between *Sears, Roebuck* and the matter before it. *Sears, Roebuck* represents a line of cases involving an agency's decision to publish material given to it by the challenging party. These cases focus on an agency's decision whether to grant or deny Freedom of Information Act ("FOIA") requests that would disclose plaintiffs' private information if granted. Because the "final agency action" in these cases is the decision on the FOIA request, and not publication *per se*, they are clearly inapposite to the case before us. *See Pharmaceutical Mfrs. Ass'n v. Kennedy*, 471 F. Supp. 1224, 1229 (D. Md. 1979).

[6] 7 U.S.C. § 430 (1982). In *Hearst Radio*, the court did not mention whether publication and dissemination of the Blue Book were authorized by statute.

been reconsidered carefully since 1948. During the thirty-five years since the issuance of the decision in *Hearst Radio*, the Supreme Court and lower courts have developed a more expansive interpretation of the term "agency action" than the one suggested by *Hearst Radio*. *See, e.g.*, *FTC v. Standard Oil Co. of California*, 449 U.S. 232, 238 n.7 (1980) (holding that FTC issuance of a complaint meets the APA definition of "order" and therefore is "agency action," even if not "*final* agency action") (quoting broad language of APA legislative history defining "agency action"). Indeed, we find it troubling that literal adherence to the *Hearst Radio* rule in a case like this one would preclude judicial review under the APA of an agency's dissemination of information that is concededly false and, therefore, completely inconsistent with the statutory purpose of promoting a prosperous agriculture.[7] Moreover, because the Federal Tort Claims Act expressly preserves sovereign immunity from suits for money damages for libel and slander, 28 U.S.C. § 2680(h) (1976), the agency would also be insulated from civil tort liability.

With these considerations in mind, we believe that *Hearst Radio* may no longer be a viable precedent; we are therefore disinclined to find that no "agency action" has taken place. However, we need not reconsider *Hearst Radio* at this time because the statute of limitations requires reversal in this case. Accordingly, we will defer any reexamination of *Hearst Radio* to another day.

B. *The Statute of Limitations*

Assuming, *arguendo*, that the agency decision to disseminate the Beltsville test results constitutes agency action, Impro's case still runs afoul of the six-year statute

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[7] 7 U.S.C. § 427 (1982) sets forth the statute's policy "to promote the efficient production and utilization of products of the soil . . . and to promote a sound and prosperous agriculture and rural life."

of limitations applicable in this case.[8] Under the APA, Impro may challenge only "final agency action." APA § 10(c), 5 U.S.C. § 704 (1982). On review of the record, however, we find that each event that might be deemed final agency action occurred substantially more than six years before Impro filed its complaint.

First, two events that conceivably constitute final agency action occurred prior to 1975. The *decision to disseminate the test results* occurred prior to 1970, when the agency submitted the article to the AJVR for publication. This complaint was filed in 1981. It can hardly be argued that that "action" fits within the six-year limitations period. Nor does the agency's *decision to disseminate reprints of the article* fit within that period, since it is clear that reprints were distributed as early as 1971. *See Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 6-7 (D.D.C. Sept. 2, 1982) (Memorandum and Order), *reprinted in* J.A. 73-74. Since both events took place more than six years ago, review of both is barred by the statute of limitations.[9]

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[8] 28 U.S.C. § 2401(a) (Supp. V 1981) provides in pertinent part: "Except as provided by the Contract Disputes Act of 1978, every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues." As the language of § 2401(a) makes clear, the section applies to both equitable and legal claims. *See Saffron v. Department of Navy*, 561 F.2d 938, 946 (D.C. Cir. 1977) (McGowan, J., concurring), *cert. denied*, 434 U.S. 1033 (1978); *Werner v. United States*, 188 F.2d 266, 268 (9th Cir. 1951); *cf. Screven v. United States*, 207 F.2d 740, 741 (5th Cir. 1953); *Heritage Pullman Bank & Trust Co. v. United States*, 480 F. Supp. 54, 57 (N.D. Ill. 1979). It also establishes the period available for judicial review of the validity of administrative decisions. *See Crown Coat Front Co. v. United States*, 386 U.S. 503 (1967). We therefore have no doubt that § 2401 limits to six years the time period available to Impro to seek judicial review of the alleged agency action in this case.

[9] Nor does each reissuance of the reprint start the statute of limitations anew. The decision to release reprints was made

Second, we have been directed toward no activity that occurred during the six years prior to filing that amounts to final agency action. Impro argues that final agency action occurred in 1981, when a USDA administrator responded to the last of numerous inquiries by Impro about USDA's position on the Beltsville test and report, J.A. 88-89, and stated his belief that the agency's actions were sound. J.A. 111. Impro therefore contends that the statute of limitations began to run in 1981. We disagree. Impro pursued its own informal routes of inquiry for ten years and then decided to characterize its 1981 letter to USDA as a request for a *final* resolution. Thus, it argues, the agency's response to the 1981 letter constituted final agency action. This line of analysis is patently specious. For one thing, it is absurd to argue that the last date of inquiry is the relevant date for statute of limitations purposes. For another, it is surely a frivolous contention to suggest that USDA is somehow bound by Impro's self-serving characterization of the 1981 letter as a request for a final ruling.

Plainly, the cause of action accrues when the "right to resort to federal court [is] perfected." *Oppenheim v. Campbell*, 571 F.2d 660, 662 (D.C. Cir. 1978). In the agency context, the logical inference is that the cause of action accrues when all statutorily required or permitted agency review has been exhausted.[10] In this case, where

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more than ten years ago, and Impro points to no evidence suggesting that a conscious, independent decision was made with any subsequent reissuance.

[10] Of course, the statute may be tolled if plaintiff did not know, and could not reasonably have known, that it had been injured. *See Japanese War Notes Claimants Ass'n v. United States*, 373 F.2d 356, 358-59 (Ct. Cl.), *cert. denied*, 389 U.S. 971 (1967). In this case, Impro alleged as early as November 7, 1969, in a letter to USDA scientists, that a report of the Beltsville test was libelous and defamatory. Defendant's Ex. 1, Attachment to Response to Plaintiff's Memorandum in Opposition to Defendant's Motion to Dismiss or, Alternatively, for Summary Judgment (June 23, 1982).

no formal review procedures existed, the cause of action accrued when the agency action occurred. Impro's last letter to agency officials in no way affected rights, or altered the status quo, so as to constitute a date of accrual. *See Provisioners Frozen Express, Inc. v. ICC*, 536 F.2d 1303, 1305 (9th Cir. 1976) (request for further proceedings on an issue does not create a right to judicial review of original proceeding). Moreover, a contrary rule would provide parties with an easy means to circumvent the statute of limitations applicable to actions under the APA, simply by writing a letter requesting reconsideration. We therefore conclude that Impro's action under the APA was barred by the statute of limitations.[11]

We note, in addition, that Impro's complaint also asserts that USDA violated its Fifth Amendment right to due process. The District Court did not entertain this assertion, apparently because it found that the APA provided ample means to give Impro the injunctive relief it sought. Because we cannot discern from the pleadings the precise nature of this constitutional claim, we remand to the District Court for further proceedings on that issue alone. In so doing, we emphasize that we take no position on the merits of Impro's claim.[12]

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[11] Impro appears to argue that it is not bound by the constraints of the APA because its action is grounded solely on 28 U.S.C. § 1331 (Supp. V 1981). As a result, it contends, it need not prove "agency action" is implicated. Brief of Appellee, p. 37. In making this argument, Impro overlooks the requirement of § 1331 that the action arise under the Constitution, laws, or treaties of the United States. Impro fails to point to any federal law, other than the APA, to be enforced, and it has offered no grounds on which we could imply such a right to sue from any statute. Impro therefore is bound by the constraints of the APA.

[12] On remand, the District Court first must determine whether Impro's constitutional claim passes the threshold test set out in *Bell v. Hood*, 327 U.S. 678 (1946). To pass that test, Impro must demonstrate that its alleged claim under the

C. Implied Remedies on Behalf of the Government

USDA counterclaims that Impro is marketing its product, Whey Blend, without a license, and that the Government should be permitted to enjoin Impro from selling Whey Blend on the basis of an implied civil remedy under the VST Act.[13] The Act authorizes criminal sanctions

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Constitution is neither "wholly insubstantial" nor "frivolous." 327 U.S. at 682-83. Second, if plaintiffs indeed assert a colorable constitutional claim, the District Court must determine whether it satisfies the six-year statute of limitations for civil actions against the United States. 28 U.S.C. § 2401(a) (Supp. V 1981). If it turns out that the constitutional claim is based on the same claim we have decided here—the decision to publish the article—simply with a new label attached, it, too, should fail.

Third, if Impro's claim falls within the statute of limitations, the District Court must then assess whether Impro in fact has suffered any damages. After a hearing, the District Court found that the AJVR article contains errors in its description of the test *methodology* but concluded nonetheless that the test *results* were misstated. This conclusion is difficult to fathom because the court pointed to no evidence that the article misconstrues the efficacy—or lack thereof—of Impro's product. Indeed, Impro's failure to present to USDA data suggesting otherwise, and its decision not to challenge the denial of its license application, counsel caution in determining whether Impro has been damaged by the errors in the article.

Finally, we note that the District Court's finding that the article is false and misleading is in no respect dispositive of the question whether its dissemination amounts to constitutional defamation, if that in fact is the basis of Impro's constitutional claim. Neither the elements of common law defamation, *see* RESTATEMENT (SECOND) OF TORTS §§ 558, 559 (1977), nor of constitutional defamation, *see Paul v. Davis*, 424 U.S. 693 (1976), are met by a simple finding of falsehood.

[13] USDA filed two counterclaims. The first sought an injunction on an implied remedy. The other claim alleged that Impro's interstate marketing of worthless products constituted a violation of the VST Act and a burden on interstate commerce, and sought to enjoin such sales as a federal common law public nuisance. The District Court pointed out that the

alone. *See* 21 U.S.C. § 158 (1976). The Government concedes that the legislative history does not indicate that an implied remedy is in order. Brief for Appellant, p. 28. In so doing, it acknowledges *sub silentio*, as the District Court did explicitly, *see Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 5-7 (D.D.C. Apr. 7, 1982) (Memorandum and Order), *reprinted in* J.A. 42-44, that it fails to meet the strict standard for implying causes of action from statutes silent on the question. *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 571 (1979). The essence of the Government's argument is that courts should be more willing to imply civil remedies on behalf of the Government than on behalf of private persons, and that this case merits such an implied remedy. For this proposition, USDA cites *Wyandotte Transportation Co. v. United States*, 389 U.S. 191 (1967), in which the Supreme Court implied a civil remedy in favor of the Government because, the Government here asserts, existing criminal penalties failed to deter the misconduct prohibited by the statute at issue. By analogy, the Government argues here that criminal penalties under the VST Act are inadequate, and that a civil remedy should be implied as a result. The Government fails to point to any

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nuisance claim was predicated solely on the alleged VST Act violations and that, since the VST Act did not authorize the Government to seek injunctions against violations, "the Government may not create that authority merely by styling its complaint as one in nuisance." *Impro Products, Inc. v. Block*, No. 81-1284, slip op. at 9 n.1 (D.D.C. Apr. 7, 1982) (Memorandum and Order), *reprinted in* J.A. 46 n.1. We agree. We note, also, that a contrary holding would enable *any agency* limited by statute to criminal enforcement procedures to claim that the violation of the statute is a public nuisance, and to seek a civil injunction. We decline to take such a step. Especially when Congress has provided a particular remedy, "a court must be chary of reading others into it." *Transamerica Mortgage Advisors, Inc. (TAMA) v. Lewis*, 444 U.S. 11, 19 (1979); *see also National R.R. Passenger Corp. v. National Ass'n of R.R. Passengers*, 414 U.S. 453, 458 (1974).

evidence that it has unsuccessfully pursued the VST Act's criminal penalties against Impro, or in any way to demonstrate that the Act's criminal penalties are inadequate. Thus, assuming, without deciding, that the Government's construction of *Wyandotte* is proper, we believe that the Government has failed to offer anything more than conclusory statements about the VST Act's inadequate remedies and consequently has not even met the *Wyandotte* standard it advances. Finding that the Government has offered no convincing basis on which to imply a civil remedy, we affirm the decision of the District Court denying the Government an injunction under the VST Act.

CONCLUSION

For the reasons set out above, we reverse the decision of the District Court in part, affirm it in part, and remand this case for further proceedings.

So ordered.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NO. 82-2447

Impro Products, Inc.

v.

John R. Block, Secretary of
Agriculture of the United States

Appellant

BEFORE: Wright, Wald and Edwards, Circuit Judges

ORDER

The petition for rehearing of Appellee Impro Products, Inc. filed January 30, 1984 presently before the Court. Appellant has submitted a response to that petition as directed by the order of February 7, 1984. The Court has considered the submissions of both parties and on consideration thereof, it is

ORDERED by the Court that the petition for rehearing is denied.

Per Curiam

For the Court:

GEORGE A. FISHER, CLERK

By: Robert A. Bonner
Chief Deputy Clerk

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IMPRO PRODUCTS, INC.,
Plaintiff,

v.

Civil Action No. 81-1284

JOHN R. BLOCK, Secretary of
Agriculture of the United States,
Defendant.

MEMORANDUM AND ORDER

In this action plaintiff originally challenged the validity of a test conducted in 1966-67 by the Department of Agriculture (USDA or Agriculture) to assess the efficacy of certain animal biologics produced by the plaintiff and as to which plantiff sought a license to distribute in interstate commerce. Since the action was filed, extensive discovery has been conducted by both sides and numerous pretrial motions have been presented and decided. By a series of earlier rulings, the issues have been refined and narrowed[1] to a sole remaining issue *viz.* whether a certain article, prepared by scientists at Agriculture, published in the August, 1970 issue of the American Journal of Veterinary Research (AMVR Article or Article), and released by Agriculture to any inquiring party, accurately reports the results of that test.

A hearing was held July 12-16, 1982 to clarify the underlying factual issues. The parties have submitted

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[1]See Impro Products v. Block, C.A. No. 81-1284 (D.D.C. April 7, 1982), *further disposition* (D.D.C. May 5, 1982), *further disposition* (D.D.C. June 25, 1982), *further disposition* (D.D.C. July 9, 1982), *further disposition* (D.D.C. July 28, 1982).

extensive briefs including proposed findings of fact and conclusions of law. The matter is now ripe for decision.

Upon consideration of the submissions of the parties and the relevant portions of the record herein, the Court concludes that the AMVR does contain several false or misleading statements, and that the release of the article by Agriculture in its present form constitutes arbitrary and capricious action and an abuse of discretion.

I. BACKGROUND

The background of this case has been discussed in some detailed in our earlier rulings, *See* Rulings cites fn. 1, *supra,* and therefore only a brief review is required here.

Plaintiff is a manufacturer of products used in connection with animal and human health. In 1965, it applied to Agriculture for a license, under the Virus, Serum and Toxins Act of 1913, 21 U.S.C. §§ 151-158 ("VST Act"), for a product which later became known as "Whey Antibody Blend" ("Whey Blend"). Whey blend is produced from the milk of cows, the udders of which have been infused with specific disease antigens. Plantiff claims that injection of the product 5-7 days prior to freshening [calving] will improve the health and milk production of cows.

After reviewing plaintiff's application, the Veterinary Biologics Division of Agriculture ("VBD") issued plaintiff a temporary license to market Whey Blend. That license expired in September, 1967. To date Agriculture has denied all further applications for a license to market Whey Blend submitted by plaintiff. Plaintiff has never challenged the denial of its license applications.

After plaintiff applied for a license, scientists with the USDA's Agriculture Research Service ("ARS") became interested in plaintiff's products. Upon review of plaintiff's application, they concluded that the data supporting plaintiff's claims of increased health and milk production were inadequate. They determined that, in the interest of scientific research, and to facilitate further evaluation of

Plaintiff's license application, ARS would conduct a controlled scientific study of the efficacy of the Whey Blend.

The ARS scientists met with plaintiff's representatives on several occasions and developed a project outline, or protocol, defining the goals and methods to be used in the test. (Plaintiff's Exhibit 249-1, 249-2, 249-3). The protocol stated that the objective of the test was "to determine whether or not injection of 50 c.c. of [Whey Blend], 5-10 days prior to calving, will increase milk production," *Id.* at 1. Approximately 500 cows, divided into two groups with relatively equal milk production capacities, were to be used in the study. One group was to be given a placebo, while the other would be administered Whey Blend. The effects on milk production and the health of the cows were to be recorded. The test data was to be gathered and analyzed as quickly and efficiently as possible.

The test began in October, 1966 and was completed in December, 1967. The procedures actually utilized in the test varied somewhat from those outlined in the protocol. The number of cows was reduced from 500 to 400. The cows were derived from nine distinct herds. Each herd was divided into 2 groups, with relatively equal milk production capacity. In four herds, the Whey Blend was tested against 0.9% NaCl, a scientifically accepted placebo. In the remaining herds, the Whey Blend was tested against natural whey, derived from the milk of the subject herds. The comparison of Whey Blend to natural whey was added to the test to determine if the whey produced from udders infused with antigens, the method by which they Whey Blend is produced, would increase milk production more than natural whey.

The goals of the test, as conducted, also deviated from the project outline. During the course of the study, the ARS scientists decided to evaluate the effect of the Whey Blend on the breeding efficiency and general health maintenance of cows. They did so by gathering data concerning instances of mastitis, retained placenta and other aspects

of the test cows' health. (Testimony of Dr. Plowman, Hearing Transcript 405-415, Testimony of Dr. Smith, Hearing Transcript 525-526.) ("H. Tr.___"). No change in the schedule for injecting cows with Whey Blend was made, despite the fact that the recommended times for injection to produce these health benefits, differed from the recommended injection times for increasing milk production.

The test did not attempt to approximate the accuracy and controlled conditions of an experiment conducted in a laboratory. Rather, it was conducted as a field study which attempted to evaluate the efficacy of the Whey Blend when used "under the same conditions that would be used in the future by dairymen." (Testimony of Dr. Plowman, H. Tr. at 349). Therefore although the plaintiff's instruction recommended that Whey Blend be administered by a veterinarian, the dairymen whose herds were used in the test were asked to inject their cows with the Whey Blend. The responsibility for recording the data essential to the test, *viz.* time of injection, time of calving, milk production yields, etc., was left to these same dairymen.

The dairymen did not pay meticulous attention to detail in the conduct of the test. Some of their records were incomplete, while others were inaccurate. More importantly, the recommended time for injection was not closely followed. Fewer than 1/3 of the cows in the study were actually injected with the Whey Blend during the recommended 5-10 day period prior to calving. (Plaintiff's Exhibits 263 p.6; 265; 267-D; Testimony of Dr. Smith H.Tr 557-560).

The test, as conducted, did not support plaintiff's claims of increased milk production. The test data, as analyzed by the ARS scientists, failed to demonstrate a significant increase in milk production attributable to the Whey Blend. Nor did the test results show any increase in breeding efficiency or improvement in the general health of the cows.

The results of the test were summarized in an article

authored by the ARS scientists and published in the August 1970 issue of American Journal of Veterinary Research. Am *J. Vet. Res.*, Vol. 31, No. 8, pp. 1485-1488 (August, 1970). (A copy of the article is appended to this Order.) The article reviewed the materials and methods utilized in the test and concluded:

> Under the conditions of the experiment, the whey antibody preparation did not cause any increase in milk production. There was no evidence that the preparation reduced the occurrence of mastitis, retained placenta, or uterine infection; nor that it reduced the average number of services per conception. *Id.* at 1488.

Copies of the article have regularly been released by Agriculture to any interested parties. Since 1971, Agriculture has responded to inquires regarding plaintiff's products by sending the inquiring party a copy of the article, together with a statement that plaintiff has no license to sell the Whey Blend in the interstate market. Although the article was published in a scientific journal intended for use by persons well versed in veterinary science, Agriculture has not restricted release of the article to scientists. Copies of the article have been sent not only to veterinarians and state agricultural offices, but also to dairymen and distributors of agricultural products.

Plaintiff contends that the article contains numerous false and misleading statements, and that release of the article by Agriculture has injured its business. Thus, plaintiff requests that we enjoin Agriculture from the further release of the article.

For the reasons stated below, we agree with the plaintiff that, because it contains false and misleading information, further release by Agriculture of the article in its present form must be prohibited.

II. DISCUSSION

The authority under which Agriculture tested the Whey Blend and released the test results is codified at 7 U.S.C. § 430 as follows:

> The Secretary of Agriculture may purchase in the open market from applicable appropriations samples of all . . . serums . . . or analogous products, . . . sold in the United States, for the detection, prevention, treatment, or cure of diseases of domestic animals, test the same, and disseminate the results of said tests in such manner as he may deem best.

This generous grant of authority permits Agriculture considerable discretion in the manner in which tests of animal biologics are conducted. In an earlier ruling, we held that this authority was sufficiently broad as to foreclose judicial review of the methodology utilized in conducting such tests. *Impro Products v. Block*, C.A. No. 81-1284 D.D.C. July 28, 1982). Thus, plaintiff may not challenge the propriety of Agriculture's actions in conducting the test on grounds that Agriculture deviated from the agreed protocol. Agriculture was free to conduct the test in any manner it deemed fit. It was not bound by the project outline developed prior to the conduct of the test. *Id.*

Although plaintiff may not challenge the manner in which the test was conducted, it may challenge the manner in which the test results were disseminated. The standard of a review applicable to such a challenge is whether the release of the test results is "arbitrary, capricious, or an abuse of discretion." *Id.* at 6 Although our review under this standard is limited, the release of inaccurate information cannot be justified even under this deferential standard. While Agriculture's discretion in the release of test results is broad, it is not free to release information which is false or misleading.

We find the article contains several statements which we deem false or misleading. For example:

(1) The most glaring inaccuracy refers to the manner in which Whey Blend was adminstered to the subject cows. The article states that "[i] accordance with instructions provided by the manufacturer, each treated cow was

innoculated subcutaneously with 50 ml. of the whey antibody preparation 5 to 7 days before the anticipated date of calving." *Am J. Vet. Res.*, Vol. 31, No. 8, p. 1486 (August, 1970). This statement is in error in two aspects. First, the manufacturer's instructions recommended injections not only 5 to 7 days prior to calving, but also again during the lactation period whenever milk production was below normal. None of the cows in the test were reinjected when milk production was below normal. Thus, the Whey Blend was not administered "in accordance with" manufacturer's instructions as the article states. Second, and more importantly, fewer than 1/3 of the treated cows were actually injected 5 to 7 days prior to calving. Thus, the statement that "each treated cow was innoculated . . . 5 to 7 days before the anticipated date of calving" (Emphasis added) is clearly inaccurate.

In an attempt to justify these inaccuracies, Agriculture argues that variations in the time and manner of injection do not impede the effectiveness of the Whey Blend. Whatever the merit of this argument,[2] the fact remains that the article does not accurately report the manner in which the treated cows were administered Whey Blend. If the ARS scientists assumed that the time of injection was unimportant, the article should have so stated.

(2) The article also reports inaccurately that the test methodology was developed in conjunction with the plaintiff. It states "[t]he design of the experiment was agreed to by the representatives from Impro Products, Inc., and Veterinary Biologics Divisions, ARS, USDA."*Id.* at 1486, fn. c. While it is true, as noted above, that plaintiff

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[2]Throughout this litigation, the plaintiff has maintained that the time of injection is critical to the effectiveness of the Whey Blend. Nevertheless, some variation in the time of injection apparently is acceptable. Plaintiff agreed to an expansion of the injection time period from 5 - 7 days to 5 - 10 days when the project outline was developed. However, in plaintiff's view, any additional deviation in the injection time frame will diminish the effectiveness of Whey Blend. (Testimony of Robert Collins, H. Tr. 30-31).

agreed to the preliminary project outline, that outline was not followed during the course of the test. Agriculture was free to deviate from the agreed upon protocol during the course of the test. However, once it chose to alter the test procedures and goals without plaintiff's agreement, it was not free to report that the "test design was agreed to by [plaintiff]."

(3) The article does not reveal that the data from two distinct herds was combined in the final data analysis. The test was performed on 8 private cooperator herds and on the ARS herds at Beltsville, Maryland. At the time of the study, the Beltsville facility had two distinct herds: the North Herd and the Breeding Herd. When the test data was analyzed, the data from these two herds was combined. This combination of data is significant for two reasons. First, there is general agreement amongst the scientists involved here that between-herd comparisons are not valid in tests such as this. Yet, the combination of data from the North Herd and the Breeding Herd effected such a between-herd comparison. Second, the combination masked evidence of the effectiveness of the Whey Blend. The data showed that Whey Blend provided a significant increase in milk production in the Breeding Herd. But, when the data from the two herds was combined, the increase in the Breeding Herd was offset by the decrease in the North Herd. Thus, the apparent benefit of the Whey Blend to the Breeding Herd was never revealed or discussed.

(4) The article does not reveal that crossbreeds were used in the study. The use of crossbred cows is significant because they are generally considered unpredictable and are rarely used as subjects in tests such as the instant test. Moreover, there are no Mature Equivalent Factors ("ME Factors") for crossbreeds.[3] Although no accepted ME

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[3]The milk production capacity of cows varies with age. A ME Factor is a factor utilized to translate a cow's present milk production capacity to that it will achieve when it reaches maturity — its years of maximum production. The factors are essential for analyzing data in a milk production study.

Factors are available for crossbreeds, the ARS scientists translated the milk production levels of the crossbreeds in the study to their expected mature production levels. The factors utilized in this translation were developed by the ARS scientists from their own data on crossbreeds. Concededly, the ARS scientists were free to use crossbreeds in the study and to utilize milk production factors generated from their own data, but the use of crossbreeds and the application of such self-generated factors should have been noted when the test results were released.

Agriculture attempts to justify these misleading statements by noting that the article was published in a scientific journal, intended for use by an audience acquainted with the problems inherent in scientific research. In its view, a scientist reading the article, aware of the difficulties involved in a field study, would expect some deviation from the protocol and problems with data analysis. The scientist reader would evaluate the content of the article in light of these difficulties. In short, the scientist would read into the article the problems inherent in a field study and would evaluate the results of the study accordingly.

Whatever the merit of this argument, it has no force where the article is released to laymen. A scientist may be able to evaluate a study in light of its deficiencies, but we do not believe a layman is equipped to do so. A layman does not have a working knowledge of the problems inherent in scientific research. A layman most likely will accept the results of the test as reported, without qualification based on the difficulties involved in the study. Thus, when a report of a scientific study is released to a layman, extra care must be taken to ensure that the methodology and results of the study are accurately reported.

III. CONCLUSION

The AMVR article does not accurately report the results of the study. Thus, its continued release must be prohibited. Agriculture is free to release the results of the test to the

public, but it must do so in a manner which fairly and accurately recounts the methodology and the problems involved in the study and the conclusions reached therein.

IV. ORDER

In accordance with the foregoing, it is this 2nd day of September, 1982

ORDERED that the United States Department of Agriculture is hereby enjoined from releasing copies of the article, published in the August 1970 issue of the American Journal of Veterinary Research, *Am. J. Vet. Res.*, Vol. 31, No. 8, pp. 1485-1488, discussing the test of plaintiff's product conducted by the Veterinary Research Service in 1966-67; and it is

FURTHER ORDERED that any report of the test released by Agriculture must contain a fair and accurate account of the problems involved in the conduct of the test, including, but not limited to: the variations in time of injection from the manufacturer's suggested time of injection, the use of crossbred cows in the study, and the apparent benefit of the product evidenced in the Breeding Herd data; and it is

FURTHER ORDERED that each side shall bear its own costs; and it is

FURTHER ORDERED that this action is hereby dismissed.

Howard F. Corcoran
JUDGE

APPENDIX D

Whey Antibody Preparation: Effects of Preparatum Injection on Milk Production in Dairy Cows

J.W. Smith, Ph.D.; C.A. Kiddy, Ph.D.; R. D. Plowman, Ph.D.; W.D. Schultz, Ph.D.; N.W. Hooven, Jr., M.S.

SUMMARY

The efficacy of inoculating cows with a whey antibody preparation just before they calved was evaluated in 8 private cooperator herds and in the herd at Beltsville, Md. The cows in each herd, due to the calve between October, 1966, and March, 1967, were allotted to 2 groups according to lactation number and milk yield. In each herd, 1 group was given 50 ml. of the whey antibody preparation and the other was designated control. In 4 of the herds, the control group was given 50 ml. of 0.9% NaCl solution, and in the other 5 herds, the control group was given 50 ml. of whey obtained from bulk milk from the herd at Beltsville, Md. According to Dairy Herd Improvement Association (DHIA) production records and to the health and breeding information recorded by the dairymen, there were no significant differences between the cows given whey antibody preparation and controls. There was no indication that the whey antibody preparation increased milk production or reduced health problems.

Colostrum contains high concentrations of antibodies which provide the newborn calf with some protection against disease organisms in the first few weeks of its life. Speculation and controversy have arisen over the proposal that milk from cows immunized by intramammary infusions might be used orally to treat specific diseases in individuals past the neonatal stage of life.[3] There is general agreement that specific antibodies appear in a cow's milk in response

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Received for publication July 25, 1969.

From the Animal Husbandry Research Division, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, Md. 20706

August, 1970.

to infusion of her mammary gland with antigens. The controversy is: where are the antibodies produced and can such antibodies be absorbed from the intestine of adults and subsequently provide passive protection against disease organisms. [1, 2]

Theoretically, specific antibodies, derived from milk could provide protection against a specific organism when the antibodies are injected, as opposed to being fed. Thus commercial products were developed. [a] The product used in this study was produced by infusing the udder of healthy, pregnant cows with bacterial antigen. Beginning 3 weeks prior to parturition, each cow was given a 5-ml. intramammary infusion once a week until one week after parturition. Individual cows may have been given antigen derived from one or more heat-killed organisms. The colostrum from the inoculated cows was discarded and, beginning 5 days after parturition, appoximately 400 kg. of milk was collected from each cow. Whey was prepared and was pooled with whey from other cows; this was clarified and bottled for distribution. The products were made available for injecting cows to protect them against, or to treat, a number of diseases and to increase lactation milk yield. [b] The product used in the study reported here was dreived from cows inoculated with a mixture containing *Staphylococcus spp., Streptococcus spp, Pseudomonas spp., Klebsiella pneumoniae,* and *Escherichia coli.* The manufacturer's printed material indicated that use of the preparation resulted in increases in milk production as great as 1,000 kg./year. The data provided by the manufacturer in support of this statement were inadequate; it was apparent that other factors may have been responsible for the increased milk yields attributed to the

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[a] With this in mind, Impro Products, Inc. Waukon, Iowa, has been producing and selling, within the state of Iowa, *patented products from "immune bovine lactealsecretion" for the past several years.*

[b] In 1966, Impro Products, Inc. submitted data to the Veterinary Biologics Division, Argicultural Research Service, U.S. Department of Agriculture, and applied for a license to permit interstate shipment and sale of "Whey Antibody Blend" to increase lactation milk yield.

product. All of the data seemingly concerned herds in which the product was administered by veterinarians treating specific herd problems. In several instances, all cows in a given herd were treated, and the total change occurring during the ensuing year was attributed to the product. In a few herds, comparisons were made between treated and untreated cows in the same herd. In some of these herds, cows which had retained fetal membranes, breeding difficulties, mastitis, or other conditions resulting in low milk production were treated before their next lactation. Other cows in the same herd were considered controls. Efficacy of treatment then was evaluated on the basis of production changes in succeeding lactations for both groups. Since cows in the treated group had problems in the proceding lactation, they were almost certain to have improved milk production, more than the control cows, in the subsequent lactation. Since there were not controlled experiments, the present study was done as a large-scale field evaluation on using the whey antibody preparation to increase milk production. [c]

MATERIALS AND METHODS

The whey antibody preparation [d] was provided by the manufacturer for testing. In accordance with instructions provided by the manufacturer, each treated cow was inoculated subcutaneously with 50 ml. of the whey antibody preparation 5 to 7 days before the anticipated date of calving. Two control groups were defined. In the 1st group of herds, control cows were inoculated with 50 ml. of (saline solution) and those using a naturally occuring control cows were given 50 ml. of filtered whey obtained from milk produced by the herb in Beltsville, md. (herd 8). The object was to compare the results of using the commercial product with those using sham treatment

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[c] The design of the experiment was agreed to by representatives from Impro Products, Inc., and Veterinary Biologics Division, ARS, USDA.

[d] Impro M:B:A. Mastitis. Blend Antibody, Impro Products, Inc. Waukon, Iowa.

(salina soultion) and those using a naturally occurring whey preparation. The 3 inoculums were supplied to the cooperating dairymen in bottles labeled with only the numbers 1, 2, or 3 for saline solution, filtered whey, and commercial whey antibody preparation, respectively,

Each cooperating dairyman was visited by at least one of the authors and on the basis of the DHIA records and breeding information, cows in each herd were allotted to 2 comparable groups. In making these allotments, cows due to calve between October, 1966, and March, 1967, were paired as closely as possible on the basis of number of lactations, production in the previous lactation, and date of expected calving. First-lactation heifers were paired by sire and expected calving date. One of the groups was selected at random to be given the whey antibody preparation (inoculum 3), and the other was designated control (given either saline solution or filtered whey). Each dairyman was provided a list of the cows assigned to each treatment number, a supply of the inoculums, and sterile disposable 50-ml. syringes and needles. The cooperating dairymen were instructed that they were evaluating 2 of 3 products, 1 of which was a commercially available product that might increase milk production. However, the dairymen were not given the identites of the inoculums. Each dairyman was instructed to administer 50 ml. of the designated inoculum subcutaneously 5 to 7 days before a given cow calved and to record the date and the number of the inoculum (1, 2, or 3) which was administered. Each dairyman was also provided with forms for recording abnormalities such as dystocia and mastitis.

Production information was obtained from DHIA records. The comparisons are based on 305-day mature equivalent (ME) production. Records of cows which were not given the designed injections or which were removed from the herd before the milking at least 150 days were deleted before the data were analyzed. Production records for all cows removed from the herd for any reason after 150 days' lactation were extended to a 305-day basis, using DHIA extension factors. Complete lactation records of less than 305 days were used without extension. One of the

TABLE 1—Comparison of Milk and Fat Production for Cows Injected with 0.9% NaCl, Whey, or Whey Antibody Preparation

Herd	Mean 305-day ME (kg.) No. of cows	Milk	Fat	Mean 305-day ME (kg.) No. of cows	Milk	Fat
		0.9% NaCl				
1	42	6,265	237	45	6,276	234
2	19	6,005	252	18	6,087	258
3	19	4,457	225	22	4,477	200
4	48	6,552	246	41	6,789	281
Group mean		6,031	241		6,101	240
Group total	128			126		
		Whey				
5	13	6,871	265	11	6,473	258
6	9	6,451	241	9	5,796	216
7	17	6,118	235	23	5,742	215
8	20	7,205	268	20	7,348	285
9	14	7,027	263	14	7,019	252
Group mean		6,716	255		6,512	246
Group total	73			77		
Grand mean		6,312	246		6,257	242
Grand total	201			203		

ME+mature equivalent.

herds in which the controls were given saline solution was sold and transferred from the area before the study was completed. Because of this, production records of 32 saline solution-inoculated cows (av. 178 days' lactation) and 4 whey antibody preparation-inoculated cows (av. 241 days' lactation) were extended. In addition, records of 4 saline solution-inoculated cow 9av. 17S days' lactation) and 4 whey antibody preparation-inoculated cows (av. 188 days' lactation) were extended because individual cows were removed from the herd. In the herds in which controls were given filtered whey, records of 7 filtered whey-inoculated cows (av. 239 days' lactation) and 15 whey antibody preparation-inoculated cows (av. 216 days' lactation) were extended.

During the experiment, it was suggested that we evaluate the breeding efficiency of the respective groups. This evaluation was based entirely on data from the herd record prepared by the dairymen.

RESULTS

The number of cows and the 305-day ME production for each group are shown (Table 1). The differences in production in herds for the groups given saline solution vs. those given whey antibody preparation and groups given filtered whey vs. those given whey antibody preparation were not significant, as determined by analysis of variance. Valid direct comparisons cannot be made between controls given saline solution (inoculum 1) and those given filtered whey (inoculum 2) because the groups were in different herds. Status of health and reproduction data are summarized (Table 2). The recorded instances of mastitis, retained placenta, and uterine infection were slightly higher in the cows treated with whey antibody preparation than in either the controls given saline solution or the controls given filtered whey. The differences were very small, however, and must be considered as chance occurrences. The services per conception for cows which conceived were very similar for whey antibody preparation-treated cows and controls in each comparison.

TABLE 2—Summary of Health and Reproductive Information for Cows Injected with 0.9% NaCl, Whey, and Whey Antibody Preparation

Item	0.9% NaCl vs. whey antibody Preparation	Whey vs. whey antibody Preparation
Number of cows having:		
Mastitis	23 vs. 24	24 vs. 26
Retained placenta	4 vs. 4	1 vs. 5
Uterine infection	1 vs. 3	4 vs. 5
Reproductive performance		
Number of cows diagnosed pregnant	102 vs. 106	63 vs. 59
Average number of services per conception	2.15 vs. 2.21	1.75 vs. 1.78

DISCUSSION

Similiarity of production averages in the group given saline solution vs. the group given whey antibody preparation and in the group given filtered whey vs. the group given whey antibody preparation clearly indicates that there were no differences which could be attributed to treatment. Statistical analysis confirmed this conclusion. On theoretical grounds, the results are not surprising. Although passive immunization is of proved value in treating some diseases, it is usually on the basis of specific antibodies for particular pathogens. In the present experiment, antibodies against a collection of specific pathogens isolated in one area at one point in time were used in anticipation of possible infection of the treated cows. The failure of the whey antibody preparation treatment to influence production or affect health status, as measured in the present experiment, could be attributed to 1 or more of the 3 main reasons:

1) Pathogens encountered by the treated cows were not reactive with any of the antibodies in the whey antibody preparation.

2) Whey antibody preparation was absorbed and eliminated from the body too soon after it was injected to be effective.

3) Antibody content of the whey antibody preparation may have been too low to be effective. In the present experiment, an attempt was not made to determine what was in the whey antibody preparation. The product was accepted as presented and was assumed to contain antibodies.

Under the conditions of the experiment, the whey antibody preparation did not cause any increase in milk production. There was no evidence that the preparation reduced the occurrence of mastitis, retained placenta, or uterine infection; nor that it reduced the average number of services per conception.

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